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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,607	12/12/2001	Darcy Wayne Greep	14458.41	7181

22913 7590 05/12/2004

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EXAMINER

ROANE, AARON F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 05/12/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/021,607

Applicant(s)

GREEP ET AL.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-10, 12-20, 22-24, 26-29, 33-35, 37, 38, 40, 41 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-10, 12-20, 22-24, 26-29, 33-35, 37, 38, 40, 41 and 43-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29, 33-35, 37, 38 and 44-47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 63 and 64 of copending Application No. 10/021,532. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the product and method of coating an electrosurgical tip that deal with either a hydrophilic/hydrophobic mix polymer or a water-soluble polymer. Other than this difference, which is not a major distinction, the dependent claims read almost identically.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-10, 12-20, 22-24, 26-28, 40, 41 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 17, 40 and 43 recite “a copolymer of a hydrophobic monomer, polymer or material and a hydrophilic monomer, polymer or material.” Although recitation of a monomer or polymer are clear, the examiner has found no reference within the specification as to what the “material” may be. Since specification is unclear as to what a material may serve as a hydrophobic material and a material may serve as a hydrophilic material, the examiner interprets the term “material” as broad as possible to including

anything that maybe used in a coating that has hydrophobic or hydrophilic characteristics and has applied the art.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-23, 26-31 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garito et al. (USPN 4,754,754) in view of Jones et al. (USPN 6,132,427) in further view of Fan et al. (USPN 5,295,978).

Regarding claim 1,2, 4, 7, 14, 17 and 22, Garito et al. disclose the claimed invention including an "RF output socket" (11) and a hand piece (20), see col. 2, lines 49-68.

Garito et al. fail to disclose a multi character coated electrode tip. Jones et al. teach the method, step or use of a device including a multi-layered coated tip electrode with a base coating (16) of ceramic in order to provide a wear resistant cover, see col. 3, lines 4-31.

Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to

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overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. Additionally, Fan et al. teach the method, step or coating of with a water-soluble polymer material which "becomes lubricious when exposed to body fluid". The fact that Fan et al. disclose a coating having hydrophilic material that can be interpreted as attracting water and Applicant's assertion on page 9, ¶ 030, lines 4-8, that a multicharacter material that attracts water to the surface and lubricates the surface creates a low shear, sacrificial layer. The recitation of lubricious nature of the polymer coating meets the claimed limitation. Finally, since Fan et al. disclose that the coating process is done with solvents (solvents some of which happen to be hydrophilic and other solvents that happen to be hydrophobic) the copolymerization of hydrophilic and hydrophobic materials is inherent. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al., as taught by Jones et al. to provide the electrode tip with a multi-layered coating in order to improve wear resistance, and as further taught by Fan et al. to improve the coating by using a combination of hydrophilic and hydrophobic polymers in order to provide an abrasion resistant coating to overcome the shortcomings of earlier coatings and to use a polymeric coating that becomes lubricious when exposed to body fluid in order to provide improved coating performance.

Regarding claim 3, Garito et al. in view of Jones et al. disclose the claimed invention, see col. 4, lines 13-23.

Regarding claims 5, 15, 18 and 23, Garito et al. disclose the claimed invention except for the pores base material wherein the multi-character material occupies at least a portion of the pores. Jones et al. teaches the inclusion of a conductive tip comprising a porous metal of roughened stainless steel, see col. 7, lines 22-26, col. 5, lines 1-7 and figures 5 and 6, element 130 and claim 25. Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. The hydrophilic/hydrophobic material of Fan et al. will inherently occupy the pores. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al., as taught by Jones et al. to provide the inclusion of a conductive tip comprising a porous metal of roughened stainless steel to the electrode tip with a multi-layered coating in order to improve wear resistance, and as further taught by Fan et al. to improve the coating by using a combination of hydrophilic and hydrophobic polymers that inherently occupy the pores in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings.

Regarding claims 8 and 9, Garito et al. in view of Jones et al. disclose the claimed invention except for the water-soluble polymer comprising at least one of polyethylene oxide, polyethylene glycol or a copolymer of ethylene oxide. Fan et al. teach a method and use of "poly(ethylene oxide)" as the water-soluble polymer (an atom polymer) in order to overcome the shortcomings of earlier coating polymers, see col. 3, lines 28-43.

Therefore at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al. in view of Jones et al., as taught by Fan et al. to use “poly(ethylene oxide)” as the water-soluble polymer in order to overcome the shortcomings of earlier coating polymers.

Regarding claims 10 and 24, Jones et al. disclose the claimed invention except for the water soluble polymer having “a radical scavenger that reduces damage to the base layer material during a process of gamma sterilization.” Fan et al. teach a method and use of providing a large number of coatings and their equivalence, including a polymer coating containing “organic radicals,” see col. 5, lines 7-66. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Jones et al., as taught by Fan et al., to alternately use a large number of polymer coatings some including “organic radicals.” The examiner interprets radical scavengers, organic radicals and a radical as the same, i.e., a chemical unit that functions as a single unit, is chemically inalterable and has an unpaired electron. Since Fan et al. disclose so many alternative polymer coatings (as does Applicant), the disclosure of Fan et al. actually teaches an equivalence of the variety of polymer coatings. Additionally, the phrase “that reduces damage to the base layer material during a process of gamma sterilization” is intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.



Regarding claims 12, 13, 27 and 28 Garito et al. in view of Jones et al. disclose the claimed invention except for the inclusion of carrying deposits of a factor that further includes at least one of an antibiotic, a healing, an anti-adhesion, an anti-tumor or a tumor necrosis factor. Fan et al. teaches the use biocompatible polymeric abrasion resistant surfaces including formulated additives with antimicrobial or other pharmaceutically effective agents” in order to overcome the shortcomings of earlier coatings and provide a more varied method and wider range of coatings and their properties, see col. 2, lines 43-68. Therefore at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al in view of Jones et al., as taught by Fan et al. to use biocompatible polymeric abrasion resistant surfaces with included formulated additives with antimicrobial or other pharmaceutically effective agents” in order to overcome the shortcomings of earlier coatings and provide a more varied method and wider range of coatings and their properties.

Regarding claims 16 and 26, Garito et al. in view of Jones et al. disclose the claimed invention except for using a multi-character material that includes a charged unit. Fan et al. teach the method, step or device that includes a metallic or ammonium ion, co. 5, lines 41-68 and col. 6, lines 1-3.

Regarding claims 19 and 20, Garito et al. in view Jones et al. disclose the claimed invention that includes a conductive tip comprising a porous metal of roughened stainless

steel, see col. 7, lines 22-26, col. 5, lines 1-7 and figures 5 and 6, element 130 and claim 25. Furthermore, Jones et al. disclose a method of applying the ceramic coating layer over top the roughened substrate by spraying using a plasma gun. Therefore, the ceramic coating layer is inherently porous since it lies atop the roughened substrate.

Regarding claims 40, 41 and 43, Garito et al. disclose the claimed invention including an "RF output socket" (11) and a hand piece (20), see col. 2, lines 49-68. Garito et al. fail to disclose a multi character coated electrode tip. Jones et al. teach the method, step or use of a device including a multi-layered coated tip electrode with a base coating (16) of ceramic in order to provide a wear resistant cover, see col. 3, lines 4-31. Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. Additionally, Fan et al. teach the method, step or coating of with a water-soluble polymer material which "becomes lubricious when exposed to body fluid". The fact that Fan et al. disclose a coating having hydrophilic material that can be interpreted as attracting water and Applicant's assertion on page 9, ¶ 030, lines 4-8, that a multicharacter material that attracts water to the surface and lubricates the surface creates a low shear, sacrificial layer. The recitation of lubricious nature of the polymer coating meets the claimed limitation. The accepted meaning of "amphiphilic" is interchangeable with applicant's disclosed meaning of multicharacter material (see page 8, last line of ¶ 27). Finally, since Fan et al. disclose that the coating process is done with solvents

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(solvents some of which happen to be hydrophilic and other solvents that happen to be hydrophobic) the copolymerization of hydrophilic and hydrophobic materials is inherent. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al., as taught by Jones et al. to provide the electrode tip with a multi-layered coating in order to improve wear resistance, and as further taught by Fan et al. to improve the coating by using a combination of hydrophilic and hydrophobic polymers in order to provide an abrasion resistant coating to overcome the shortcomings of earlier coatings and to use a polymeric coating that becomes

#### ***Response to Amendment***

The examiner acknowledges the amendments to the claims. The amendments to claims 1, 17, 40 and 43 do not overcome the prior art. The amendments to claims 29 are significant and once a terminal disclaimer is filed claims 29, 33-38 and 44-47 will be distinct over the prior art.

#### ***Response to Arguments***

Applicant's arguments filed 2/12/2004 have been fully considered but they are not persuasive. The copolymer of a hydrophilic monomer, polymer or material and a hydrophobic

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monomer, polymer or material is disclosed by the Fan et al. reference. Although Fan et al. do not explicitly use the words “copolymer of a hydrophilic monomer, polymer or material and a hydrophobic monomer, polymer or material”, Fan et al. do disclose the coating comprising a hydrophilic solvent (material) and a hydrophobic solvent (material). The different solvents (coating) form bonds (which is the reason why the coating mixture adheres to the substrate) and thus, inherently the coating involves the copolymerization of a hydrophilic monomer, polymer or material and a hydrophobic monomer, polymer or material.

Once a terminal disclaimer is filed claims 29, 33-38 and 44-47 will be distinct over the prior art and copending application 10/021,532.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*  
May 3, 2004

*Michael Peffley*  
MICHAEL PEFFLEY  
PRIMARY EXAMINER